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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,571	04/01/2004	B. Ron Johnson	15070.6.2	1232

7590 05/22/2008

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,571	JOHNSON, B. RON	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed January 25, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The amendment to the claims filed on January 25, 2008 does not comply with the requirements of 37 CFR 1.121(c) because the status of the claims is not clearly marked in all the claims, see for example, newly added claim 36 does not indicated that it is (New).

Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) Claims . Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original),

(Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered)

(1) Claim listing. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1 –5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the

claims shall not contain any other part of the amendment.

(2) When claim text with markings is required. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the

status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn — currently amended."

(3) When claim text in clean version is required . The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original, " "withdrawn " or "previously presented " will constitute an assertion that it has not been

changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn " or "previously presented." Any claim added by amendment must be indicated with the status of "new " and presented in clean version, i.e., without any underlining.

(4) When claim text shall not be presented; canceling a claim .

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled " or "not entered. "

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled " will constitute an instruction to cancel the claim.

(5) Reinstatement of previously canceled claim. A claim which was previously canceled may be reinstated only by adding the claim as a "new " claim with a new claim number.

Newly submitted claim 36 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method for treating herpes virus induces disordered tissue is unrelated because this is an entirely

different search category that corresponds to the Group IV invention. This was a non-elected group in the election made on September 6, 2007.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 36 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has amended composition claims 1-13 to recite a method of treatment, therefore the claims are rejoined and examined. Further, applicant as amended instant claims 25-35 generic to viruses, bacteria or fungus. Therefore these claims are rejoined and examined.

Claims 1-19 and 21-35 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-13 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 27 recite the method wherein said anti-infective composition comprises at least one quaternary ammonium

halide compound having an alkyl group with at least 6 carbons. With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%-60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had **no upper limit** and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement. In the instant case, the specification describes a quaternary ammonium compound having an alkyl group with between 6 and 18 carbons. Hence claims 1 and 27 recite no upper limit and cause the claim to read literally on embodiments outside the range of 6 to 18 carbons in the alkyl radical, and does not meet the description requirement.

Claims 4-13 are indefinite to the extent that they read on the rejected base claims in that they do not contain an upper limit for the carbons in the alkyl radical.

Claim Rejections. 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-17, 19, 21, 25-28, and 30-35 are rejected under 35 U.S.C. 102(b) as being

anticipated by Beauchamp et al. U.S. Patent No. 5,753,270 A.

Beauchamp et al. teach a composition for treatment of skin afflicted diseases such as cold sores, fever blisters, Herpes Simplex II (genital herpes), psoriasis, acne or eczema and the like (column 3, lines 10-13) and Herpes Simplex I (herpes labialis) comprising applying to the skin an aqueous solvent system (column 3, lines 50-53) that comprises an antiseptic such as an alcohol and a quaternary ammonium antiseptic compound (column 4, lines 4-33). The alcohol can be isopropyl alcohol or the like, in water and the quaternary ammonium antiseptic compound may be benzalkonium chloride in an organic skin penetrating solvent (column 5, lines 25-35). There does not appear to be a recitation of a penetration inhibiting compound in the composition disclosed in Beauchamp et al., thus it is substantially free of penetration inhibiting components. Regarding the limitation of claim 14 drawn to penetration of the skin in a rapid manner so as to form a reservoir of the treatment composition within the disordered tissue without rapidly diffusing beyond the disordered tissue, Beauchamp et al. teach immediately modifying the dried keratin layer of the epidermis for rapid penetration into the skin and for relief of pain, itching and destruction of viral and bacterial cells which are the source of the diseased skin condition (column 3, lines 28-34). It does not recite diffusion beyond the disordered tissue. Regarding the manner of

application, it is generally understood that "apply liberally" would imply that the formulation is rubbed on the affected area (column 5, lines 56). The liquid is applied directly using a cotton swab or other type of applicator (finger) (see column 6).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 7-9, 18, 22-24, 29are rejected under 35 U.S.C. 103(a) as being unpatentable over Beauchamp et al. U.S. Patent No. 5,753,270 and Remington's Pharmaceutical Sciences, 1975.

Beauchamp et al. teach a composition for treatment of skin afflicted diseases such as cold sores, fever blisters, genital herpes, herpes labialis, psoriasis, acne or eczema and the like (column 3, lines 10-13) comprising applying to the skin an aqueous solvent system (column 3, lines 50-53) that comprises an antiseptic such as an alcohol and a quaternary ammonium antiseptic compound (column 4, lines 4-33). The alcohol can be isopropyl alcohol or the like, in water and the quaternary ammonium antiseptic compound may be benzalkonium chloride in an organic skin penetrating solvent (column 5, lines 25-35). Regarding instant claim 10, Beauchamp et al., does not disclose oil in the composition. Further, instant claim 19 is drawn to a method wherein the composition is free of penetration inhibiting components. Since these components seem to be oil as noted in instant claim 10, it reads on the prior art that recites a method for treatment of cold sores, fever blisters, genital herpes, herpes labialis, psoriasis, acne

or eczema and the like (column 3, lines 10-13). Regarding the limitation of claim 14 drawn to penetration of the skin or stratum corneum so as to form a reservoir of the treatment composition within the stratum spinosum, Beauchamp et al. teach immediately modifying the dried keratin layer of the epidermis for rapid penetration into the skin and for relief of pain, itching and destruction of viral and bacterial cells which are the source of the diseased skin condition (column 3, lines 28-34). The claim elements appear in the prior art in the same configurations, serving the same functions, to achieve the results suggested in prior art, treatment of viral and bacterial disorders.

Beauchamp et al. does not disclose the method wherein the carrier is 20-40% isopropyl alcohol or 70% isopropyl alcohol. Beauchamp however, discloses that the solvent is combined with water in an amount in the range exceeding about 50%. This amount overlaps with 70%. The recitation of the work “about" in instant claim 7 causes about 40 % isopropyl alcohol carrier to read on the prior art amount of about 50% (column 5, lines 25-26).

Beauchamp et al. does not disclose the method wherein the composition is no longer visible after about 2 minutes, however, all ingredients are water soluble in an aqueous solvent system. It is not expected that the medicament would be visible. Further, since isopropyl alcohol is a volatile substance, any remaining medicament that is not absorbed would volatize away, and not be visible. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald(205* USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In

such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Regarding the limitation of claim 22 wherein the method of treatment is by application of the composition by rubbing or compressing the disordered tissue, Remington's Pharmaceutical Sciences, 1975, recites that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). It would have been made obvious to one of ordinary skill in art at the time it was made to rub or compress the disordered tissue when applying the composition motivated by the teaching of Beauchamp et al. that the composition is topically applied and the teaching of Remington's Pharmaceutical Sciences that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph).

Regarding claims 23 and 24 drawn to treatment of disordered tissue caused by smallpox virus and anthrax bacteria; Beauchamp et al. teach the destruction of viral and bacterial cells which are the source of the diseased skin condition by topical application to the skin (column 3, lines 3-34). The prior art showed destruction of viral and bacterial cells by topical application of the composition of an organohalide such as benzalkonium chloride and isopropyl alcohol in water. Therefore, it would have been

obvious to one of ordinary skill in the art to substitute the smallpox viral cells or the anthrax bacterial cells the predictable result of the destruction of the viral and bacterial cells.

Response to Arguments

Applicant asserts that Beauchamp or any other art does not teach the combination of providing a penetrating treatment composition as claimed, coupled with applying the treatment composition in a manner that causes or allows the treatment composition to form a reservoir of the treatment composition within the stratum spinosum. In response, the claim elements appear in the prior art in the same configurations (benzalkonium chloride combined with isopropyl alcohol and water in an amount greater than about 50%), serving the same functions (applied or rubbed with an applicator or otherwise applied), to achieve the results suggested in prior art (treatment of skin afflicted diseases such as cold sores, fever blisters, genital herpes, herpes labialis, psoriasis, acne or eczema and the like).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the desired result in a single application vs. multiple applications by the prior art) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is well established that the specification teaches an invention, whereas the claims define the right to

exclude. *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 [227 USPQ 577] n.14 (Fed. Cir. 1985).

Applicant asserts that the method of Remington's Pharmaceutical Sciences would penetrate through the skin and into the patients "circulation". In response, penetration into the hair follicles is not the same as penetration into the "circulation or bloodstream". Hair follicles are oil glands. Further, applicant appears to be applying in the same way and the composition, if applied to a region containing hair follicles would be absorbed in the same way.

Regarding Applicants' assertion that Beauchamp only discloses a single example of a quaternary ammonium halide compound, a reference is good not only for what it teaches by the direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re Opprecht* 12 USPQ2d 1235, 1236 (Fed. Cir. 1989); *In re Bod*e 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Regarding applicant's assertion that Beauchamp "may" include oils such as menthol, thymol and eucalyptol, the inclusion of these agents in the composition and method of Beauchamp is not required.

Applicant asserts that Beauchamp does not teach or suggest treating lesions caused by smallpox and/or anthrax. In response, Beauchamp et al. teach the destruction of viral and bacterial cells which are the source of the diseased skin condition by topical application to the skin (column 3, lines 3-34). The prior art showed destruction of viral and bacterial cells by topical application of the composition of an

organohalide such as benzalkonium chloride and isopropyl alcohol in water. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the smallpox viral cells or the anthrax bacterial cells the predictable result of the destruction of the viral and bacterial cells.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

May 13, 2008

/Brian-Yong S Kwon/

Acting SPE of Art Unit 1614